

NBSIR 76-997

ETIP

Proceedings of Procurement Practices Symposium - Health Care October 14 - 16, 1975

Sponsored by:

Veterans Administration
Washington, D. C. 20420

Experimental Technology Incentives Program
National Bureau of Standards
Washington, D. C. 20234

Final Report

February, 1976

Prepared by
Experimental Technology Incentives Program



EXPERIMENTAL TECHNOLOGY INCENTIVES PROGRAM (ETIP)

The Experimental Technology Incentives Program was initiated in fiscal year 1973 as part of the President's program to learn how the Government could stimulate technological innovation. The objective of the program is to learn how the Federal Government can provide policies and incentives which will encourage greater technological innovation by the private sector. Broader application of innovative technology could lead to the amelioration of several national problems such as a low rate of increase in productivity, negative trade balances, environmental pollution, and public health and safety.

The interrelation of the Government and private sector is complex and not enough is known to predict the effect on technological innovation of a change in government policy. Consequently, various hypotheses regarding possible federal policy are being tested with analyses and experiments.

Four policy-related program areas have been identified for investigation and experimentation. The program areas refer to procurement practices, regulatory practices, civilian R&D funding practices and federal financial assistance policies. In each of these, new or modified federal policy is being tested in cooperation with responsible federal agencies.

In addition to these initial policy questions, the program will conduct analyses and exploratory studies to provide an improved basis for choice of policy questions for future investigation as well as to permit more effective direction and evaluation of the already selected policy questions.

The accompanying report was prepared under contract as part of the ETIP program of the National Bureau of Standards. Statements contained in this document represent the views of the originating organization and do not necessarily reflect those of the National Bureau of Standards.

Director
Experimental Technology Incentives Program
National Bureau of Standards
U. S. Department of Commerce

NBSIR-76-997

**PROCEEDINGS OF PROCUREMENT
PRACTICES SYMPOSIUM - HEALTH
CARE
OCTOBER 14 - 16, 1975**

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U.S. DEPARTMENT OF COMMERCE, Elliot L. Richardson, *Secretary*
James A. Baker, III, *Under Secretary*
Dr. Betsy Ancker-Johnson, *Assistant Secretary for Science and Technology*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Acting Director*

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SYMPOSIUM OBJECTIVES

- To investigate ways for improving interaction between health care personnel and the manufacturers of hospital products and systems, so that the demands of all hospitals for improved and innovative products and systems can be more adequately met.
- To explore various means available for encouraging innovation and more efficient technological change: from initial research, through product development, user testing and evaluation, marketing and purchasing, to post-delivery assistance for the using services.
- To develop approaches that will permit hospitals to acquire the latest technologies more expeditiously and economically through the procurement process.



**plenary
session**

PROCUREMENT PRACTICES SYMPOSIUM

HEALTH CARE

Sponsored by

Experimental Technology Incentives Program (ETIP)
National Bureau of Standards, U.S. Department of Commerce

Veterans Administration (VA)

The Honorable Richard L. Roudebush
Administrator of Veterans Affairs
Veterans Administration

There is something about being called on to administer a large government program or a large government agency that soon leads you to the conclusion that you need all the help you can get.

I reached that conclusion about a year ago. The President had made it final and official that I was to be responsible for an agency that has some 200,000 employees, that spends billions of dollars and that has as its potential clientele nearly half the population.

He administered the oath of office and said, "I expect you to do a good job."

There is an urgent sound to a remark of that kind that encourages you to look around for all possible friends and all possible resources. I have been on this lookout ever since.

I am glad to be with you this afternoon at this symposium and I am glad to know that the Experimental Technology Incentives Program is developing and progressing as a link between government and industry that will enable both to do a better job.

I think it has great potential as a source of help for the Veterans Administration and it is a pleasure, personally and officially, to attend an event in which that potential may be discussed and explored.

For the entire 200 years of our Nation's existence there have been programs of help for the men who fought our wars and provided our defense. This country has done more for its veterans than any other in history.

But, for at least half of our history, benefits were of the most rudimentary kind... token payments in cash or land, meager medical care and the promise of a place to live in old age.

It was not until this century when large numbers of citizens were called on to fight overseas wars that a system of care and benefits worthy of the name was developed.

And it was not until World War II that activities on behalf of veterans became realistic in terms of what could be done rather than partial programs or symbolic actions that eased the Nation's conscience.

It was then that the decision was made to provide training, housing and job assistance that allowed new veterans to become established as productive civilians without the hassles earlier veterans had experienced.

And it was then that the decision was made to provide medical facilities for veterans that were as complete, as advanced and as sophisticated as any in the country. It was decided to make them training and research centers of high quality and to involve them and affiliate them with the best schools and institutions existing.

Today there are 171 VA hospitals and 213 VA outpatient clinics and VA has annual medical expenditures of more than \$4 billion.

I think it is obvious that any agency that is entrusted with that much of the taxpayers' money for one of its functions has large responsibilities in the handling of that money.

I am talking about the responsibility to avoid the waste that is always a great danger in a large operation, but I am talking about other things beyond the mere avoidance of waste.

A large agency with a large budget can be creative to a certain extent in the way it uses its funds, because its size and diversity of operations present alternatives not available to smaller units.

A large agency can be aggressive, if you will, in the way it uses its funds, bargaining for the best transactions and controlling in many ways the circumstances of its spending.

And, if an agency has these abilities, I think the cause of good government demands that they be used... and used as extensively and as effectively as possible.

Thus, VA is not only a part of the ETIP program but subscribes to its purposes and its methods wholeheartedly.

We think this program can cause several things to happen... not right away and suddenly, but over a period of years and gradually, as we learn how to apply and expand the principles that underlie this new aid to better procurement.

We will get better products and equipment into the VA health care system. They will meet our needs more closely than other items have. They will be safer. They will last longer. They will be more efficient from an energy use standpoint. They will be environmentally sound. They will, in the long run, be more economical.

Most important, they will help us carry out our mission in a more effective way.

The end product of this venture will be better care for veterans, relief of suffering, a greater chance to cure illness and injury... and do it faster... and a greater opportunity to restore people to useful living.

There will be other ramifications. If we are successful in setting new standards of care, in creating new procedures and in procuring better products and equipment, health care outside the VA system will benefit as other hospitals and institutions make use of what we have done.

Other government agencies for which VA provides procurement services and guidance will benefit.

And there will be the economic consequences that received so much attention as this program was being formulated... better use of government funds and a greater volume of business for participating firms and industries.

This is, of course, a simplified and general view of the ETIP program from the vantage point of VA management.

I have offered no suggestions as to how these things may be made to come about. I have given no examples of areas in which the ETIP concept may be expected to produce the most significant or the most prompt results.

I hope your workshop discussions during this symposium will lead to at least some preliminary decisions in these matters.

I hope you will make progress in articulating and refining the roles of industry and of VA and other government agencies in this program.

I hope you will give impetus to the thought and effort required in fitting specification development, research, testing and evaluation, training and other activities necessary to this effort into a workable arrangement.

I hope you will make some headway in determining exactly how a transfer of benefits between the public and private sectors may be brought about.

I will not tell you how to do these things. It is not my place to. I don't know how to.

But I offer you my full support and that of VA, not just for today or for the days of this symposium but on a permanent basis, because I think this program is not only innovative and progressive but necessary and sensible.

The opportunities it gives us to increase our productivity and our efficiency would be reason enough to proceed as rapidly as possible.

When you add the human reasons for our proceeding...reasons that only those who are ill or injured and those who care for them can appreciate fully...we are left without a choice.

We who are responsible for the success of VA medicine feel that we must always be ready to do what we can to improve patient care...that we must work hard, that we must continue to learn and that we must never be completely satisfied with what we are doing.

The ETIP program offers new help to VA and we intend to take full advantage of it.

I appreciate the opportunity you have given me to talk with you and I hope you find this symposium productive.

Dr. Ernest Ambler
Acting Director
National Bureau of Standards

I should like to welcome all of you here to the National Bureau of Standards and note that we are very pleased to join with the Veterans Administration in the sponsorship of this symposium.

Oliver Wendell Holmes once said, "Knowledge and timber shouldn't be much used until they're seasoned." ETIP, or our Experimental Technology Incentives Program, is in the business of defining and evaluating how to season our knowledge and timber so they can be "much used" to increase American productivity. ETIP was established by Presidential mandate at NBS in March of 1972. Specifically, it was established to develop and test governmental policies that will provide incentives to the private sector of the economy to invest in innovation and technological change. In reality, what we're trying to do is to stimulate a more rapid transfer of technology from the laboratory to the marketplace. The ETIP mission is twofold: First, trying to find ways to achieve these goals; and second, identifying ways to get these answers built into the policies and practices of the Federal Government.

ETIP is providing an arena for experiments - an environment of real world learning experiences. Our basic operating strategy is the design and conduct of policy experiments in close cooperation with those agencies whose responsibilities and activities are relevant to ETIP's goals. These operations are being carried out in four different areas: procurement, regulation, civilian research and development, and small business.

Why should we, in the Federal Government, have a program doing this? Very simply because in a developed economy such as ours, technology is an extremely important element in the system. Many of our key industries - such as agriculture, health care, manufacturing, and energy production are strongly dependent on technology. The National Commission on Productivity has reported that technology is the largest single contributor to productivity growth in the United States. Department of Commerce figures show that our foreign trade balance is in surplus only with respect to technology intensive products, which thus help pay for our petroleum, raw materials, and other essential imports.

As you know, NBS is concerned with the development of new knowledge and the application of that knowledge to various sectors in this country to enhance productivity. Thus, we have been involved with technology and technological change since our founding in 1901. The legislation affecting the Bureau has been amended several times since 1901 and yet three themes have remained strong and consistent. First, we are responsible for national measurement standards. Second, we are responsible for the determination of physical constants and properties of materials; and finally, we cooperate with other government agencies. In the past 75 years, the Bureau has developed a pretty fair amount of

credibility within the Federal Government, throughout industry, and with the average consumer.

In carrying out our mission, we have long been concerned with technology transfer. One of the most vital elements in technological progress is the availability of adequate and appropriate measurement capability. The Bureau of Standards assures the availability of such capabilities by maintaining basic standards, developing measurement techniques and establishing dissemination procedures to make this know-how available at the point of use. For example, we calibrate approximately 1,300 instruments and standards for measurement per month. We have developed nearly 900 Standard Reference Materials, whose chemical and physical properties have been certified by the Bureau. More than 32,000 of these SRM's, as we call them, are sold annually for use in calibrating instrumentation in such diverse areas as pollution monitoring, optical glass production, health care and computer hardware quality control.

Through our activities with Federal, state and local governments, NBS provides measurement support in high technology areas to safeguard against radiation hazards, to minimize corrosive attacks of materials in magnetohydrodynamic generation of electric power, to model the stratosphere to assess the effects of man-made chlorofluorocarbons and many others. All of these services directly facilitate the transfer and utilization of technology.

You are here today to talk about health care products. I would like to assure you that NBS is not a stranger to this field. In fact, we have a dental research program which began in 1919. Since 1928 the American Dental Association, through our research associate program, has cooperated with the Bureau in this work. Many Americans today have fillings in their teeth which last twice as long and have superior properties as the result of materials developed at the Bureau. These materials, which are called composites, match the appearance of the teeth and last longer than silicate cement and save on replacements. The Bureau was also responsible for the development of the panoramic x-ray machine and the high-speed turbine drill.

I mentioned the Standard Reference Materials Program. In the United States there are at least 15,000 clinical laboratories which analyze billions of human serum, urine and tissue specimens each year. NBS has developed standard reference materials and reference methods to improve accuracy in clinical measurements. We have prepared 20 clinical SRM's and one reference method - that for calcium in human serum. These SRM's provide clinical laboratories

with a means to evaluate their measurements and to improve their quality control.

In another project, scientists from the Bureau have worked with an orthopedic surgeon from the George Washington University Medical Center to characterize the "cement" used in orthopedic surgery to stabilize total hip implants. The emphasis has been on determination of the physical, chemical and mechanical properties of poly-based cement as it is prepared and used in the surgical procedure. Such materials used in a total hip-joint replacement and in neurosurgical applications can help to deliver improved health care to the patient.

Quite recently the Bureau, in conjunction with the Food and Drug Administration, sponsored a workshop to discuss reliability technology for cardiac pacemakers. The workshop directed attention to the procurement and assurance of reliable, long-lived semiconductor electronic parts; the hermiticity testing of device packages and pacemaker systems; the activities of the several standardization organizations; and the use of reliability data banks and other information and service sources.

Health care delivery is one of America's largest service industries. The time has come to bring together the needs of your industry with the technical capabilities of our laboratories and let ETIP serve as the catalyst. One of the finest points that ETIP offers is the fact that it is an experiment. It is not intended to be a demonstration project. It will not be a simulation or hypothesis, but a real world opportunity for us to find that "seasoned knowledge" I mentioned earlier.

I am pleased that I really have two tasks this afternoon. The first was to welcome you, but the second is to introduce your keynote speaker, a gentleman who has been serving as Senator from the State of Maryland since 1970, J. Glenn Beall holds the same seat that was once held by his father.

A native of Frostburg, the Senator has been active in politics since 1962 when he was elected to the Maryland House of Delegates. He serves on the Commerce, Labor and Public Welfare, Budget, Special Committee on Aging, and Select Committee on Small Business. Some of his special interests are reflected in his subcommittee assignments which include: health, handicapped, employment, alcoholism and narcotics, and human resources. It is particularly fitting, therefore, that he is with us today. Thus, it is my pleasure to introduce to you an excellent human resource, Senator J. Glenn Beall.

The Honorable J. Glenn Beall, Jr.
Senator, Maryland

It is a pleasure for me to participate in this joint National Bureau of Standards and Veterans Administration conference.

I commend both agencies for sponsoring this dialogue between the manufacturers of health products and systems, health personnel, and government.

Your theme "Encouraging Innovation in Health Care Products" is most appropriate. If there ever was an area and a time which demanded imagination and innovation, that area is health and that time is now.

I do not want to be misunderstood. Health care in the United States at its best is unequalled anywhere.

But the problem is that we have not been able to deliver to all of our people, wherever they live and at a price they can afford, quality medical care.

Major problems confronting the health industry include:

1. The need to make certain that financial barriers do not prevent citizens from receiving needed health care;
2. The need to correct the medical manpower geographical and specialty maldistribution problems, and to address this Nation's growing reliance on foreign medical graduates;
3. The need to face up to the quality issues in health;
4. The need for better health planning;
5. The need to control escalating health care costs. Of all the health problems, this is the most serious and the number one concern of the public. National expenditures for health care in 1974 totaled \$104.2 billion, an 8-fold increase over the 1950 figure of \$12 billion. Another way of looking at these astronomical cost rises, which may be especially meaningful to this audience, is that in 1974, expenditures for what might be considered medical business-drugs-medical supplies and equipment - will be approximately \$14 billion, a sum which exceeds the \$12 billion spent for all of health in 1950.

Health is part of what has been labeled the "growth field of modern society" - the public service sector.

This sector employs six out of every ten Americans, and now accounts for over one-half of our GNP.

Industry has always emphasized performance and productivity. Productivity in the service sector has not received similar attention and the record of this sector is unimpressive. True, measuring productivity and performance in the service sector is more difficult. However, the rapidly rising health costs and this sector's growing importance and impact on society, make it imperative that improved productivity be pursued with a sense of urgency.

A labor-intensive industry characterized by rising costs and low productivity, should be ripe for technological and product innovations.

Technological advances in such areas as space, communications, and data processing in the last decade have been unbelievable.

Yet, technology has not made a similar impact on the health system, particularly as a vehicle to advance productivity and to contain costs.

In fact, much of the health care system continues to employ the same manual procedures used at the turn of the century. We desperately need to wed 20th century technology with 20th century research to improve the delivery of health care, and I might add 20th century procurement practices, to improve the delivery of health care.

In the 1960's, there were expectations that technology would produce a "revolution in health care." This obviously has not materialized.

Why has technology failed to live up to its expectations? There are numerous reasons, but they would include the following:

1. The diffused markets in the health field;
2. The limited success of technology to date;
3. The fears by some that technology will depersonalize health services;
4. The inability of health institutions to examine and evaluate technology and no central clearinghouse to do this job for them;
5. Lack of test sites where innovations could be tested and the results disseminated;

6. The reimbursement system and procurement policy often provide the wrong or little incentives to encourage the proper level of care or the introduction of cost-effective technology;

7. The changes taking place and contemplated in the health field such as in the organization and delivery systems; the user population (more elderly); manpower, particularly the use of paraprofessionals; and the growing role of government; and

8. The government's failure to give priority to the utilization of technology in the solving of health problems as has been done, for example, in space and defense.

As a member of the Senate Health Subcommittee, I have been very interested in research and development and the use of technology in health care delivery.

In introducing legislation, S. 723 in 1972, to establish a National Institute of Health Care Delivery, I stated:

"Since World War II, the U.S. has invested over \$20 billion in biomedical research while during this same period comparatively small investments have been made to deliver the fruits of biomedical research to the American public."

Although this measure passed the Senate on two separate occasions, it was not enacted. Nevertheless, S. 723 was the first bill introduced in the Congress calling for an expanded research effort and it helped produce an upgrading of health care delivery research with the enactment of Public Law 93-353, the "Health Services Research, Health Statistics, and Medical Libraries Act of 1974". This Act, among other things, provides a legislative mandate and calls for an upgraded National Center for Health Services Research. The Act also incorporated a number of specific features of my original bill, including the establishment of regional and two special emphasis centers, a Health Care Management Center and a Health Care Technology Center.

The Health Care Technology Center will focus on all forms of technology and their application in the improvement of health care.

The Health Care Technology Center is expected to provide the leadership and mobilize the development and the utilization of technology. The Health Care Technology Center, and such programs as the Experimental Technology Incentives Program (ETIP), must address some of the difficulties to the utilization of technology for solutions to our health problems.

In a 1972 Senate floor speech, I cited some examples of appropriate actions the Health Care Technology Center could take or promote, and I quote:

"Various agencies of the Federal Government operate their own health systems, such as the Defense Department and the Veterans Administration. These federal health systems offer the opportunity for a market sufficiently large to attract industry investment.

Second, the Federal Government could identify potential opportunity for technological solutions and solicit competitive bids through requests for proposals -- RFPs -- as is done by the Defense Department. Thereafter, there could be full funding of a prototype followed by a guarantee that a sufficient number would be purchased to insure a profit. The units produced could then be sold, loaned, leased, or donated to individuals or organizations that would use them effectively."

Technology must be developed to solve health problems. As elementary as this sounds, I am not convinced this has always been the case. There are a number of reasons for this.

Technology in the health industry usually developed independent of, rather than in cooperation with, health institutions. Many products were purchased at the whim of a physician or by a health institution to keep up with a sister institution. The health care cost crisis is and will change this. The health system does not need, nor can we afford "technological playthings" or "status symbols".

HEW has not designed or established the technology or management centers yet, but I am hopeful that this will be done before the end of this year.

Unfortunately, the upgrading of health services research, at least as far as additional resources are concerned, is not taking place. The priority which health services research deserves and requires has not been forthcoming. Evidently, some shortsighted OMB official, whose long range views and vision extends not one iota beyond this year's budget, felt such research was not important, and worst, his views prevailed.

In 1972, when my bill to establish a National Institute for Health Care Delivery passed the Senate, I deplored the inadequate funds going to health delivery research. That year, the budget was \$62 million.

Do you know what the budget will be for the National Center for Health Services Research following the enactment of PL 93-353 "Upgrading and Improving Research"? The answer is between \$23 and \$26 million, a figure which will be nearly two-thirds less than the 1972 funding level.

Considerable change is occurring in the health field. The rapidity of change is likely to accelerate in the years ahead. Given the many unknowns, the need for new knowledge, and the need to apply what we already know, I find the decline in funding for health services research deplorable and short-sighted. Such action certainly is contrary to the intent of PL 93-353 designed to upgrade health services research, and is in conflict with the explicit statements of HEW in its own "Forward Health Plan". Let me quote to you from this 1975 document:

"The Assistant Secretary for Health is placing increasing reliance on the National Center for Health Services Research for advice on what is known and being discovered about health services delivery.

High priority is placed on increased resources to enable the center to carry out its expanded mandate under PL 93-353 and to provide information and advice on health services policy."

"However, even the basic elements of the National Center for Health Services Research Legislative Mandate, including the regional health services research centers and the intramural program, cannot be implemented within available funds or staffing. Given that fact, and the growing importance the Assistant Secretary for Health is attaching to the role of the NCHSR, this forward plan places a very high priority on increasing the resources available to the Center. The National Center for Health Services Research's own forward plan for FY 1977-81 greatly increases the policy relevance of the focus of its activities, which should help to restore much needed confidence in the National Center."

I do note, however, that this forward plan is for Fiscal Years 1977-81. Hopefully, Health Secretary Cooper will be able to convince OMB and the appropriations committees of the Congress of the importance of Health Research and in next year's budget we will find funds to match the rhetoric.

The wants and needs of society present the health industry with a major challenge and great opportunities. Never before, in fact, has the opportunity for innovation in health care been greater because never before have we faced the cost-quality-service dilemma we face today.

Technology has the potential of being enormously beneficial to the health community and the public. Let us put American technology, management, and know-how to work to solve this Nation's health problems and to help us achieve our goal of quality service to all our citizens.

Joseph G. Berke
Experimental Technology Incentives Program
National Bureau of Standards

I want to extend my welcome and express my appreciation for your attendance today. This symposium, although our third in ETIP, is our first related to medical goods and services. Those of you here today are playing an important role in developing, suggesting and participating in the design and implementation of procurement experiments that will have a positive effect on the medical industry.

Today I will be sharing the podium with Mr. Clyde Cook, Director of Supply for the Veterans Administration. I will review the ETIP philosophy and try to direct your thinking to the workshops ahead, how you can contribute and what ETIP and the VA want to get out of them.

Mr. Cook will briefly touch upon the activities in the VA as they relate to current and future joint procurement experiments.

The Experimental Technology Incentives Program, or ETIP as we call it, was created as the result of the President's Science and Technology Message of 1972 and the Budget Message of 1972 and the Economic Report of the President. The budget and other documentation suggested seven possible types of experiments for the program. These were:

1. Identifying and addressing industry-wide technical opportunities;
2. Aggregation of research and development capability;
3. Assistance to inventors and small innovative firms;
4. Experiments dealing with the transfer of government-held technology;
5. Government procurement as an R&D incentive;
6. Stimulating technology through market aggregation; and
7. Evaluation of advanced technologies to enhance productivity.

As I mentioned, ETIP stands for the Experimental Technology Incentives Program and we are physically located here at the National Bureau of Standards in Gaithersburg.

Contrary to popular belief ETIP is not concerned with what new technologies are needed nor are we analyzing how much R&D support the government should provide. ETIP is a policy research program and conducts experiments and studies that will provide a data base upon which to recommend new government policies that will increase the private sector investment in technological change as well as increase the broader utilization of federally funded civilian R&D.

The ETIP mission, then, is to develop and test governmental policies that will provide incentives to the private sector of the economy to continue to invest in innovation and technological change.

The way we work is shown in this flow chart of events. First we develop an issue that we think needs attention. Initially in new areas the staff of the ETIP policy areas would initiate the issue -- currently, after almost two years of working with all levels of government, we find that many issues that fit the ETIP objectives are originating with the agencies we work with. After an issue is developed we try to find a contact, an in-house champion, at as high a level as possible in the agency to ensure approval and commitment to the issues, to supply resources to the experiment and to carry out the experiment or study for a period of time, from months to years.

Once the agency contact is established, the experiment negotiation and design begins. Here responsibilities are established, policies identified, and the experimental approach laid out. When this is complete and all parties are satisfied with the experiment plan, it goes through the ETIP approval process. This consists of the Director of ETIP, and the Director of NBS. After such approval, funds are made available to conduct the experiment. The funds are available for use in three ways:

1. As an interagency transfer to cover extraordinary expenses within an agency for the conduct of the experiment;
2. As a transfer which the agency uses to obtain the services of a contractor; or
3. ETIP can award a contract and have the contractor work with the agency in question.

After the experiments are underway the evaluation process begins to take place. Policy recommendations will then come from groups of experiments and their evaluations. Currently, the Policy Areas of ETIP using this approach are Procurement, Regulatory, Civilian R&D and Small Business.

Let me now move on to describe the Procurement Policy Area, what we are and what we do.

Our objective is to determine if procurement can be used as an incentive for industry to continue to push technology, and continue to offer new and better goods and services.

With this objective in mind, let me now digress a bit to talk about how government generally does business and its significance to the ETIP objective.

Currently, for most civilian goods and services, the government buys to the lowest common technological denominator and to the lowest initial acquisition price. This general procurement process tends to restrict the application of new technology because of price and other considerations. This present policy can and should be changed to respond to the fundamental principle of procurement -- "To get the best deal or value for the government and the taxpayer."

This principle is within the objectives of ETIP although the concept of the "best deal" may need to change. The degree to which the Federal, State or local procurement systems can be effective in stimulating technological change depends to a great measure on how purchasing officials view their responsibilities. Although the needs for new or improved products originate with the user agency or group, the purchasing department and all it encompasses must assume the responsibility and leadership to translate those needs into appropriate specifications, prescribe test methods, evaluate new innovations and determine the "best deal."

ETIP's role in the framework of experimental procurement policy is to provide the umbrella under which the experiments take place and to act as the catalyst for ensuring that the experiments do take place, evaluate the results, disseminate the information and make policy recommendations.

Let me now leave the general statements and get specific about how ETIP is working to test new procurement policies and practices. The government "clout" to provide incentives for technological change rests on the fact that the government is often the largest single buyer of commercial goods. If you add to this federal market, the state and local markets, the incentive to industry to serve the total is greatly increased.

The mechanisms whereby this government "clout" can be harnessed reside in the procurement tools. Some of the tools being tested by cooperating federal agencies in conjunction with ETIP include the use of performance specifications, life cycle costing and value incentive clauses.

You will hear a great deal more about these in the various workshops so I will not elaborate here.

In order to assess the effectiveness and timeliness of a procurement tool for encouraging technological change, it is important that ETIP through its evaluations identify and understand certain characteristics associated with industry's response to a government procurement incentive.

These characteristics are:

1. The significance of the government buy;
2. Government's knowledge of availability of technology;
3. The nature and structure of the private demand; and
4. The nature and structure of the supply and manufacturing sector.

The specifics of our ongoing experiments are provided in the pamphlet you received at registration. I will not dwell on these here.

I would like to point out that for products that are common to State and local markets as well as the Federal market, we will incorporate the experiment into our ongoing experiments with NASPO and NIGP.

Briefly our state project encompasses the fifty states through specification preparation, consensus testing procedures and uniform procurement policies for generic products.

Our local project does essentially the same thing below the state level. To the extent possible all levels of the procurement process will participate in our experiments.

To have these policy type procurement experiments be successful requires a great deal of personal attention.

Through symposia such as this one we can receive the benefit from all your collective experience. I urge you all to be outspoken, present an adversary position, and be constructive in your workshops and help us get moving.

To summarize, ETIP is interested in experiments, studies and analyses that can be the basis for recommending policy changes at all levels of government.

Clyde C. Cook
Director, Supply Service
Veterans Administration

I was mentally revising my remarks when Joe began talking about being last on the program with little left to say. He used a word that struck a memory cord when he said, "I would 'briefly' describe to you what we are doing." It reminded me of a time some years ago when I was the last speaker on the program and my assigned role was to summarize and fill in the gaps. It had been a very long program and we were off schedule, just as we are today. Late in the afternoon, the coordinator handed me a note that said, "be brief." As we got farther off schedule and people began to fidget, he handed me another note that said, "be very brief." Well, as I began my part of the program, two hours after we were supposed to adjourn, I waited for his last note. The note didn't come, but the expression on his face said, "don't speak." That's probably what I should do today.

I'll try to give you a frame of reference within which ETIP will operate in the VA. For a number of years, the VA has had a product evaluation program for the medical items used in its hospitals and clinics. In the past, this has been a rather modest program with a somewhat different thrust than we anticipate it will have under ETIP. Our product evaluation programs developed somewhat informally in response to unmet user needs. Too often, very little was known about the performance, reliability or relative quality of the various items which were being marketed for use in health care facilities. Our testing and evaluation was aimed at the rather limited objective of identifying the actual performance of these products.

Our Administrator gave you some idea of the magnitude of our operations and I feel the VA has an ideal climate for the kind of experimentation, product evaluation and new product development that ETIP offers.

Some of the other testing and evaluation programs the VA has been operating are in the area of prosthetics. There is a prosthetics center in New York City, which evaluates aids for the blind, equipment systems for spinal cord injury systems, and prosthetic and orthotic upper and lower limbs. This center has performed clinical evaluations, evaluated experimental devices, and conducted compliance testing against previously developed standards. It is probably the

most sophisticated product development program we have at the VA. Other programs include a laboratory, run by our Dietetic Service, which carries out sensory evaluations of food products, and also performs in-use testing of food service and preparation equipment, as well as a dental program to conduct comparative evaluations of dental equipment.

The VA Marketing Center, located in Chicago, Illinois, administers a general product evaluation system on a wide range of medical supplies and equipment. The Center selects new items of equipment or supplies and places them in use at selected VA hospitals. Feedback data is gathered, and this information determines what items will be standardized for use throughout the system.

The VA also contracts out for testing and evaluation services. The National Bureau of Standards tests and evaluates hearing aid performance, while our Health Service Research and Development Service contracts for safety evaluations of medical equipment.

Recently, a management consulting firm made a comprehensive study of the programs in the VA as part of a broader evaluation of the Agency. They looked at what the VA might do to share its technology and knowledge of medical supplies and equipment with a broader spectrum of the population. As is usually the case in these studies, they commended our efforts, told us about our shortcomings, and suggested a few improvements. The major deficiency that they saw was that the program lacked formal management.

Proposals came in from almost any quarter and, while that was good, it was frequently left to the proposer to decide where, what, and how the item(s) would be tested and/or evaluated. Occasionally, there was a lack of adequate evaluation protocols and procedures which affected the quality of the evaluations themselves. This firm felt that sometimes our evaluation results were not thoroughly analyzed, or if they were, the analysis was not adequately recorded or disseminated. This firm recommended that the VA establish within its Supply Service, a Testing and Evaluation Division. This division will manage a more formalized program in close collaboration with the using services represented by the professional and technical staffs of the Agency. This division will also support other programs that operate laboratories within the VA.

At this moment, we are in the process of establishing this division. ETIP is aiding us in this venture by providing funds to pay for part of the staff. The ETIP program has been merged with this new division in that in many ways they

complement each other. To repeat, I feel that the VA has an ideal climate for the kind of experimentation and product evaluation of new product development that ETIP offers. We are also working with the ETIP staff, Ross Hofmann Associates, VA Supply Service personnel, and VA professional staff, to develop product performance descriptions on several items.

The items selected were chosen not because they represented the most esoteric items in which we could identify needed improvements. We have chosen two very homely items as our beginning point. The first item is a syringe and needle destructor, which is a problem to the nursing staff and many others in hospitals. The second is a bedpan sterilizer, not a sanitizer, but a sterilizer that can be used in patient care areas. We hope to have these descriptions in the manufacturers' hands within the next 3 to 4 weeks. After that, depending on the response, then, if industry is ready to go, we are. I would like to tell you what I think the biggest difference is between our past efforts and the efforts that we think we will be undertaking with ETIP. In the past, with probably the notable exception of the prosthetics program, the primary thrust of our product evaluation has been to determine what the items being evaluated would and would not do. ETIP adds the new dimension of evaluating not only this, but also what the product should and should not do. We will then attempt to translate what it will do and what it should do into a description to the industry, of the performance requirements and the characteristics that we need.

The thrust of these performance descriptions will be to describe, in medical terminology, what the item should and should not do in terms of performance. We are trying to get away from writing technical specifications. An effort is being made to describe the performance parameters rather than giving an engineering design specification. I think the most important thing with us is that the critical input will come from our users, the staff members of VA, and the professional services. We have approximately one dozen other items which are in various stages of development into performance descriptions. It is hoped that several of these will be ready for presentation to industry over the next few months.

As Mr. Roudebush said, "We are open to all of the help we can get." We are open to any suggestions this symposium might make in terms of items we might examine for future development. We feel by beginning modestly, and moving slowly (not too slowly, we hope), we can contribute something, not only to the VA, but to the health care community at large and also to the health care industry. We hope, from this seminar, to get the assistance and the participation we need to get this program going.

WORKSHOP TOPICS

Each workshop had co-chairpersons, with representation from health care disciplines in government and the private sector, and from the manufacturing sector for health care products. Every encouragement was given for the workshops to serve as forums for frank and open discussion and the free flow of ideas, representing a broad range of opinions and diversity of interests. The six workshops were designed to cover a broad spectrum of interaction between suppliers and users, and their topics were:

1. Interaction Between the Hospital User and the Industry Supplier. There is a continuing need for close interaction between the user and the supplier of hospital products and systems, so that the needs and demands of the institutions, the staff and the patients are promptly and legitimately answered in the development of new products and systems by the suppliers. This need covers new items, innovative items and improved items.

Who should initiate interaction for such developments? Should it be industry through its research and development followed by aggressive merchandising to create demands among hospital users and patients? Or, should it be hospital and medical personnel through their experience in using products, treating and diagnosing patients, and managing medical institutions?

What procurement procedures, such as Life Cycle Costing, Value Engineering clauses, etc., can be an effective means of communication on user needs and industry response?

2. Research and Development for Innovative Products. What should be the roles of manufacturers, the health care deliverer, the public and government in R&D to encourage technological innovation? How can industry be encouraged to perform more R&D for products hospital users feel they need and that do not exist at present? Through use of specifications and standards, that reflect needs, through R&D contracts.

Is industry willing to spend the money for R&D, and by owning the production rights, respond strictly to buying contracts for innovative products without receiving the monetary award for an R&D contract? How can they be assured of a long term market, in view of diverse user opinions on most products?

How difficult is it to achieve technology transfer from other industries and disciplines to health care products?

If a research organization develops the product, what should be the patent and licensing policy?

3. Product Testing and Evaluation. To protect their reputation, as well as to satisfy regulatory agencies, manufacturers continually test their products for quality control; they also evaluate their new developments in the field to ensure that they are marketable and satisfy the needs and demands of their customers. Many hospitals feel that users should play a larger role in evaluating products offered by industry; that formal testing and evaluation centers and laboratories should be established to determine, from the user's side, whether the products meet industry's claims, as well as the quality control and specific uses required by hospitals.

How far should hospitals proceed in such specification development and testing and evaluation? How much should they duplicate the efforts industry is performing? What is the role of government in providing technical assistance?

4. Specifications. Commercial specifications for products and systems sold in the hospital field appear to be less definitive than in certain other industries. A large percentage of government specifications are design oriented in nature. Many users, as well as purchasing agents, in both the public and private sectors feel that specifications for hospital items should be of the performance type, including Life Cycle Costing and Value Engineering clauses to permit manufacturers latitude in designing details, and to protect the user in evaluating the product.

When performance specifications or Life Cycle Costing are used, ground rules must be established for testing and evaluating products. Formulas and standard tests must be followed, spelled out in advance of procurement. Testing periods both before and after delivery must be defined. Vague value judgments must be eliminated as much as possible. Differences between standards and specifications must be clarified. Are performance specifications more desirable than design specifications, why and how? How can this be accomplished in a manner that is satisfactory for both the user and the supplier?

5. Post Delivery Performance, Warranties and Training by Vendors. In the merchandising of hospital products, warranties, instruction manuals and personnel training are becoming more critical as the sophistication of medical care and diagnosis increases.

What forms should these take? How detailed should they be? How long should training programs extend? What form should they take? What are "fair" charges for post delivery assistance? What are both the user's and manufacturer's responsibilities when employees do not follow practices recommended by the supplier?

With equipment, what type of instruction manuals, parts lists and spare parts should be furnished with the initial delivery? What should be the lengths of warranty periods? On items claimed to be sterile or safe, what is the protection for the buyer in specific terms?

6. Cost Saving and Quality Improvement Through Innovative Products. How can industry be encouraged by users to develop products and systems that legitimately save labor and operating costs for hospitals and simultaneously assure better control of health care delivery?

As an example, do disposables really save money, or is efficient reprocessing the cheaper route to follow? Whose management surveys should be used - the supplier's or the user's?

How far are industry and the hospitals willing to go to definitely establish costs as a base line for the development of labor saving devices and systems?

WORKSHOP REPORTS

1. INTERACTION BETWEEN THE HOSPITAL USER AND THE INDUSTRY SUPPLIER

Co-Chairpersons: Frederick W. Bauer, M.D.
Greater Baltimore Medical Center

Donald P. Whitworth
Don Sowle Associates, Inc.

2. RESEARCH AND DEVELOPMENT FOR INNOVATIVE PRODUCTS

Co-Chairpersons: MG Robert Berstein
Walter Reed Army Medical Center

William H. Goldwater, Ph.D.
National Institute of Health

3. PRODUCT TESTING AND EVALUATION

Co-Chairperson: Colonel James G. Borman
Fort Detrick

4. SPECIFICATIONS

Co-Chairpersons: George F. Ainsworth
Hospital Bureau, Inc.

Wilbur J. Balderson
Office of Surgeon General, DA

5. POST DELIVERY PERFORMANCE, WARRANTIES AND TRAINING BY VENDOR

Co-Chairpersons: James D. Gibson
Castle Company

Dennis A. Grote
Greater Baltimore Medical Center

6. COST SAVINGS AND QUALITY IMPROVEMENT THROUGH INNOVATIVE PRODUCTS

Co-Chairpersons: David Lubin
Sinai Hospital of Baltimore

Alice H. Meyer
Greater Baltimore Medical Center



workshop 1
interaction
between the
hospital user
and the
industry supplier

INTERACTION BETWEEN THE HOSPITAL USER
AND THE INDUSTRY SUPPLIER

The discussion initially centered around the genesis of product innovation in the health field. One workshop member, an educator from MIT, contended that his studies of the subject showed that seven to ten years elapsed from the time a user -- i.e., a physician, nurse, dietician, pharmacist or whomever -- developed a device until it was commercially available. He illustrated the typical steps involved with this chart:

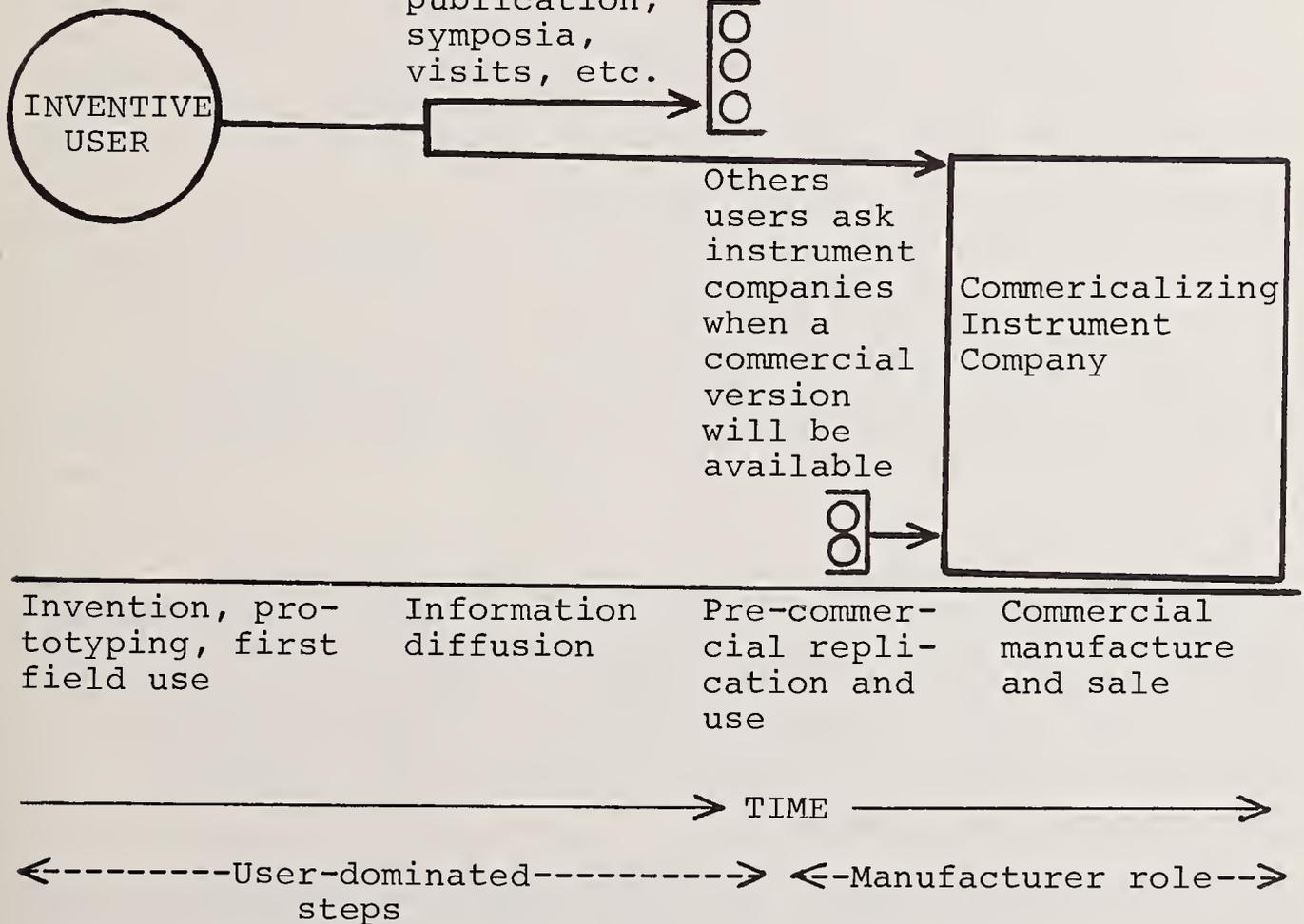
* Typical Steps in the Invention and Diffusion of a Scientific Instrument or Instrument Improvement

(1) Significant instrument improvement invented, built and used by:

(2) User diffuses results and 'how to do it' information via publication, symposia, visits, etc.

(3) A few users (or a few dozen) build their own

(4) Instrument company introduces commercial version



*Source: Professor Eric Von Hippel - "Role of the user in the Scientific Instrument Innovation Process" - Sloan School of Management - working paper 1975

Hospital oriented workshop members contended that the medical "industry" -- the manufacturers and other suppliers -- show a remarkable lack of interest in using the "work bench" development concept to promote technological change. Instances were cited where sophisticated items now on the market grew from user initiative and eventual interest on the part of the medical industry. Proponents of this philosophy expressed the view that traditionally the suppliers of medical devices depended on the user to "lead the way." This one-sided discussion served to highlight one basic question of the workshop, i.e., "Who should initiate interaction for technological development -- the suppliers or hospital and other medically oriented personnel?"

The opposing position was quick to surface. Industry representatives pointed to many convincing examples of new devices and innovative ideas that stemmed solely from industry research and development -- from industry interest in supplying a better product. Items such as disposables, specifically, operating room drapes and gowns, were mentioned. This example sparked a discussion of what is or is not progressive innovation. Problems of space required for storage of such disposables, physician acceptance, or possibly lack of acceptance and other problems were discussed. This discussion seemed to lend weight to the proposition that the hospital user is the best source of innovative ideas.

Representatives of industry injected into the discussion real problems involved in user-industry coordination and interchange of ideas. A user -- perhaps a physician -- approaches a company with an idea that is represented as a panacea for all medical problems, something that must be developed! After much research and expenditure of funds and other resources, the company comes up with what they consider to be the answer only to find to their dismay that the originator of the idea is no longer interested.

Other industry "gripes" involve (1) the difficulty in getting to the right person in a given hospital, (2) the murky channels that often exist between the professional and administrative officials that thwart them in their efforts to interest the right people in new products and ideas and, (3) the reluctance of professionals to listen to them, contending professional persons are only interested in listening to their peers.

Industry representatives contended that the difficulties encountered in getting to the persons who actually use their products -- access to the right people -- is a real detriment to industry innovations. Administrators who interfere

with their ready access to user personnel retard progress. On the other hand the discussion developed that industry-user contact had to follow an orderly process involving the officials responsible for an institution's procurement support.

Industry has trouble in its efforts to have hospital personnel "try" items. "We can't use it," or "we don't like it," is allegedly often heard before the item is ever tried. However, the suggestion that physicians and other professional personnel are inflexible and resistant to change was rejected. Industry representatives joined in rejecting this contention. It is a matter of proper approach and accessibility. Physicians, as well as others, will recognize a superior product, an improved approach. The big question is, "What is the proper approach?"

Also rejected by many was the suggestion that industry, being profit oriented was too interested in making a buck to try to find out what is best for patients and patient needs. That the progress that has been made today has been accomplished largely with industry cooperation was generally agreed to. One company represented grew to be a multi-million dollar concern from scratch by actively seeking out the valid needs of users. That the direct approach to the user they employed bypassed all administrative personnel often landed them in trouble, emphasized the need for some orderly means of communication of ideas between the right interested parties.

A question that repeatedly had been cropping up came up again at this juncture: "How do we bring industry, the hospital administrator (procurement official) and the user together in the most effective fashion to encourage item development?"

Another question that even more often emerged was: "Where is, or perhaps what is, the medical community?" Is there such a thing to which the specific points being discussed in the workshop could be addressed? If there is a "hospital community," who is/are its spokesmen? If there is not such a community, how does the businessman communicate with something that does not exist?

It was generally agreed that insofar as item development and hospital-industry communication were concerned the nation's hospitals are not a single community, and there is no apparatus to bring them together as such.

The many medical societies were mentioned as the possible catalyst that is needed. Yet they, while essential professionally, are segmented and not oriented to speak for the

device needs of the man/woman at the "work bench." Industry and professional associations interacting with the hospitals in their many environments -- private, Federal, state, municipal and other -- could be helpful, but not the total answer.

Somehow, to optimize the possibilities for item innovation, the segmented hospital "community" and the equally segmented hospital "industry" must find a way to fuse their common interests. But how?

Gaps abound! There is the gap between hospitals themselves. Hospitals in the private sector are not aware of what their sister institutions may be doing. Government hospital groups are not aware of the efforts being made within each group. Government (at whatever level) hospitals do not know what private hospitals may need that they already have developed -- or vice versa.

How to communicate in this morass of proliferation? The age-old problem cropped up again and again with the consensus that the gaps were indeed real, but no consensus on how to close them.

The lack of an "item technology" data bank to prevent duplication of effort and to promote cross fertilization of ideas was advanced. This was regarded as a good idea. However, as far as industry is concerned, the "does Macy tell Gimbles" philosophy was quite properly brought up, for it was recognized that all firms are in business to survive, and survival means to make a profit. Yet, for the medical community a developmental "data bank" was regarded as a very interesting idea.

Again and again the main thread of the initial discussion was picked up. Who has the ideas and where do we go to get them developed? Governments, vendors, hospitals don't have ideas, only individuals have ideas. The starting point at least is with the individual. Many innovative ideas have merit, many do not. All that show promise, however, should be pursued. The individual hospital can't afford in terms of money and time to live in isolation, ignorant of the technological advances others have available to them. Medical costs have risen too high for hospitals to continue to operate technologically speaking in the dark, especially when the means exist to shed light on their problems. Government keeps its ideas and follow-through to itself and the independent hospital has no knowledge that an innovation it yearns for has been developed by Government.

For private hospitals, costs of following up suggested innovations are prohibitive and hospitals are desperate for technological development but frustrated in their hopes.

Congress, in the view of industry, does not help with its hearings about high prices that do not take into consideration the high cost of initial development borne by the companies. This was brought out as a detriment to industry development.

Again the question: Is there a hospital "community"? That there is a hospital market was agreed to, but a hospital community in the conventional sense, no! There is a potential "community." Now, however, there are seven thousand hospitals with individual needs not bound together except within the several government agencies that operate hospitals, and even these are not tied together.

Over and over the discussion came back to frustrations stemming from the lack of a means of tying the hospital "community" together as one. Each private hospital is an entity, each government-operated (Federal, state and local) hospital apparatus is an entity, and there is no tie between them.

It became apparent that the flow of thought was moving toward the notion that this workshop could only do one constructive thing beyond a healthy and invigorating exchange of ideas and views. It could recommend a way to fill the voids, to plug the gaps, to tie the hospital "community" together, thus enabling ETIP-VA and all other innovative activity to be available to all to a maximum degree.

The consensus was clear, we need a "data bank," a "sounding board," a "clearing house," -- call it what you will. What is needed is a way to capture:

- Innovations in progress
- Specifications
- Lists of interested suppliers
- User organizations
- Existing, interested programs
- Lists of organizations and societies
- Tie-ins with all existing systems and organizations that will be helpful.

The information must be captured by item. It must be available for ready retrieval. It must be current.

The system must work two ways. It must be able to respond to a query for information. It must regularly publish pertinent data, output, such as ETIP-VA experiments and their

status. At the least it should be able to tell a questioner where to go for advice and information.

Whatever the system is called, names such as Health Elementary Liaison Program (HELP), health Operations Program Exchange (HOPE) -- and many others were suggested -- whatever it is called, it should be seen as the needed tie to bring the shattered hospital "community" together at least for item development purposes.

How would such a monster operate? For a monster it could be! When one considers all the supplies and equipment used by hospitals one has covered over thirty thousand items and has considered almost any item that readily comes to mind. Well, we must proceed in an orderly fashion. First, items directly related to patient care should be considered, and within that category electronic devices should be number one. Growth should be gradual until all significant hospital items are covered.

Should the Federal Government operate this system? The belief was that if it had the aura of a federally imposed program it would remain just that, a Federal "big brother" program. No, it should be a private enterprise. To get the idea off the ground, government funding is called for, probably ETIP, but only to get it moving. Industry representatives felt that industry subscribers would be sufficient to sustain an ongoing effort such as we envision. At any rate we are convinced that industry and hospital subscribers would be sufficient to sustain it, including a regular publication, listing all item improvements wherever or whenever they might be taking place or planned as well as false starts and item evaluation information.

Therefore, we recommend that ETIP undertake the development of a hospital industry information interchange data bank in four phases:

- (1) Planning and organization
- (2) Development of test program
- (3) Phase in operational program
- (4) Publicize program.

Related Matters Discussed

● An interesting discussion followed a suggestion that the hospital community could care less when a patient was sent home. Where is there a developmental effort for home oxygen (or the like) equipment? Response here rebutted the

contention that interest was lacking but seemed to agree that except in high intensity health centers the resources were not available for an effective program.

- Funding is a problem. Government medically oriented agencies are scantily funded for item R&D, though liberally funded for medical research, out of which often grows system improvement and innovation.

- Both the usefulness of and the dangers for introducing minimal performance and other standards for the evaluation of health care products was discussed at length. It was recognized that such standards can become so involved and complicated such as to exclude innovation. Nevertheless, it was recognized that the small institutions isolated by both distance and communications from the mainstream of the health care industry often could use some sort of "standards" for its evaluation of health care products, especially those which are expensive. Here, it was suggested that a better word to describe what would be needed would be evaluation guidelines rather than "standards."

- Industry people felt that government too often went overboard on specifications. They should be loose and allow for variations in item composition. Life cycle costing, while received as an interesting concept and with possible future potential in the medical field, was thought of as something only experimental at this time. It should be tried, was the consensus, but don't rush. One objection voiced was that the obsolescence factor was greater in hospital equipment than any other type of gear.

- Interaction between hospitals and industry in evolution of new ideas and products in health care depends upon the following factors:

- (1) Hospital size and type, i.e., government (Federal or state), university, teaching community hospital, non-teaching community hospital.
- (2) Various types of patients and hospital specialities represented very markedly among such institutions.
- (3) The average length of hospitalization.
- (4) The age of the institution.
- (5) The number of private versus multiple bed rooms.

● Finally, there was a discussion of why professional societies were not better represented. The idea was advanced that the notices did not reach the right people. Who are the right people -- chairmen of subcommittees perhaps. Criticism was also heard of the announcement letter -- governmentese, no schmaltz. Next time do a little Madison Avenue.



workshop 2
research and
development
for innovative
products

RESEARCH AND DEVELOPMENT FOR INNOVATIVE PRODUCTS

From the guidelines for the Symposium the members of this Workshop derived the following areas of emphasis for our discussion:

- I. What are and what should be the roles of manufacturers, health care deliverers, the public, and Government in R&D to encourage technological innovation?
- II. How can industry be stimulated to perform more R&D for products which hospital users feel they need but do not exist at present?
- III. How can industry be better assured of long-term markets and thus be willing to spend their own money for R&D?
- IV. How can technology transfer be enhanced from other industries and disciplines to health care products?
- V. What should patent and licensing policies be for research organizations which develop needed products?

While the background and general theme for this entire program suggested an emphasis on hospital deliverers of health care and on manufacturers of hospital equipment products, the members of this Workshop have tried to consider the health care field and supplier in their broadest sense. We have thus tried to develop recommendations which should be applicable to R&D for all types of medical products, including drugs, vaccines, biomaterials, and various types of medical devices and equipment used by hospitals, clinicians, laboratories, and patients. We have viewed the discussion topics first in the light of an overall pattern of relationships between the various sectors involved, and further with regard to what we regard as a somewhat logical sequence of steps in the development and use of innovative health care products.

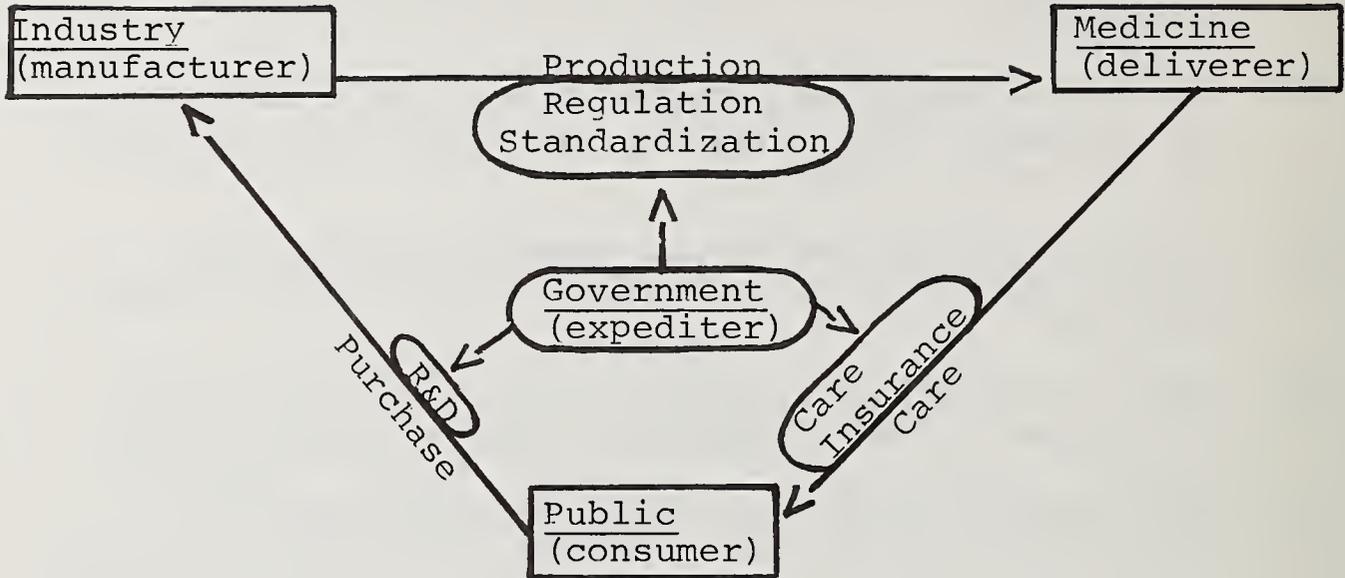
A. INTERRELATIONSHIPS BETWEEN SECTORS IN R&D FOR INNOVATIVE PRODUCTS

The Workshop sees a complex series of relationships between the various sectors involved in R&D to encourage technological innovation in health care products, with the Government

playing a central catalytic role in stimulating, controlling, and expediting the various relationships, as suggested in Figure 1.

FIGURE 1.

SECTOR INTERRELATIONSHIPS IN R&D FOR INNOVATIVE PRODUCTS



Starting with the manufacturing phase, industry develops and produces new products for the medical community. Government plays a regulatory role, e.g., Food and Drug Administration, and a standardization role, e.g., National Bureau of Standards, in seeing to the quality, reliability and safety of products thus produced for health care delivery.

The medical community, represented by many types of individuals and institutions delivers these products to the consumer public. Government plays various roles in this process, ranging from direct care, as under the Veterans Administration, Department of Defense, or Public Health Service, to provision of insurance arrangements to cover relationships between private individuals and non-Government health care providers, e.g., hospitals, clinics, and practitioners.

As the ultimate consumers of the health care products, the public pays directly, of course, for costs that have gone into these products, including in a sense the earlier R&D by the manufacturers on those products and also continuing R&D for new and improved products. Government stimulates the latter through award of funds for research and development

into new areas of product development, ranging from basic and applied research to the actual development, testing, and demonstration of new products in the clinical setting.

While the arrows in Figure 1, indicate the flow of processes in one direction only, as described briefly above, the Workshop noted that most of these processes have reverse components which provide feedback to the originator of each process.

B. IDENTIFICATION OF NEEDS

The Workshop suggests that identification of needs must be the first phase towards development of new and innovative products for health care. So that R&D and later production may be better attuned to the viability of future markets, the Workshop considers a number of potential improvements:

1. Identification of future requirements should be improved by periodic and systematic reviews of the state-of-the-art in technological fields, and of specific user needs in the consumer area.
2. While identifying various needs, greater attention must be paid to the priorities which these needs fill in a total scheme of R&D/health care requirements. Such priorities must be reviewed regularly, frequently, and systematically, as new social values or political currents determine changes in the directions of health care delivery needs and of R&D requirements to fill those needs.
3. In considering both needs and priorities for health care, attention must be given not only to original costs of new products, but also to requirements for their durability and upkeep, particularly for all types of equipment and devices. The Life Cycle Costing concept is particularly important in this connection.
4. So that needs and priorities may be most adequately considered, all sectors must be involved in determinations and decisions. While technological feasibility and delivery capability may be determined fairly adequately by manufacturers and medical communities, it is equally important to obtain public inputs into the decision process, to determine attitudes of the ultimate consumers of new products. A potentially valuable role in this process may be played by individuals with talents in the new field of "clinical engineering" who may help narrow gaps between basic biomedical research and health care delivery. It was noted that the National Academy of Sciences has acted in several

instances as a catalytic function to such interactions, bringing together representatives from the various sectors to engage in productive discourse on developing technologies; it might serve similarly in other such capacities in more extended efforts.

C. ANNOUNCEMENT OF NEEDS AND PRIORITIES.

Having arrived at decisions on directions for development of new health care products, it becomes necessary to bring these to the attention of the various sectors involved in the process. The Workshop members feel that certain current or new processes may be used to enhance such communications.

1. Periodic and regular meetings, journals, and other publications by the professional and institutional societies provide a ready and ideal means to announce various needs to other sectors. Access to and use of such communications media should be improved, and opportunity should be afforded in publications and meetings for improved communications of established needs and priorities. Annual meetings of the Association of Operating Room Nurses were mentioned as a particularly notable opportunity for such dialogue, with respect to that specific field of health care.

2. Government, through its constant interfaces with the various performer sectors, is especially able to obtain and maintain current information on many user needs and priorities. Agency publications and meetings should thus complement those of the private sector in assisting such communications.

3. A single organization should be considered as a logical central focus for such communications. Such an organization could serve many functions, such as maintaining and operating:

- a. An advisory system for public and private sector inputs into the decision process; and
- b. An information system on health care needs, including possibly a catalogue of such needs and/or a computer function which could be accessed by outside users, both of which could be kept current by suitable procedures.

Such a clearinghouse organization should preferably be located outside any one organization which pursues its own R&D functions, to avoid potential biases for R&D programs and goals of that organization, or against programs and goals of other organizations. The potential of the NAS was mentioned again in connection with such a clearinghouse function.

D. ANNOUNCEMENT OF AVAILABLE TECHNOLOGY

Given an established set of desired product needs, it is next desirable to bring these together with whatever technological advances may exist or may be developed to meet the needs. The Workshop considered a number of ways this phase may be improved:

1. The clearinghouse function mentioned under C.3, as a source for publicizing needs and priorities, might serve also to store and disseminate information regarding available technologies. A catalogue and/or computer system could serve this process just as for needs-priorities information. In a sense, the National Technical Information Service now provides such a central focus.
2. Professional and organizational societies should provide additional outlets for dissemination of information about developments in new technologies. It was noted that meetings and publications of the Health Industry Manufacturers Association now provide such a forum.
3. Mention was made also of a new technique called "computerized conferencing," now being used in New Jersey, where new technological information is introduced into a computer system by technology developers, and is accessed for such information by potential users. In turn, the latter may enter into the system their desired product needs and uses, for stimulation of R&D efforts by potential producers. Such techniques should enhance the entire process of technology transfer between different sectors and performers, including those working on various Government agency R&D programs.

E. DEVELOPMENT OF PRODUCTS

Having brought together the different inputs of consumer needs and available technologies, it becomes necessary to consider ways to stimulate the manufacturers to produce desired products for health care, given in many instances some degrees of uncertainty regarding available markets and potential advantages versus disadvantages to the manufacturers. We noted several points to consider in these connections.

1. Government agencies which are constantly in touch with various consumer sectors are in a most favorable position to assess potential markets for various products. Such efforts should be improved, particularly to provide estimates about needs for such products in terms of:
 - a. The size of potential populations who would provide the market;

- b. The availability of other products which might compete with new developments;
- c. The intensity or seriousness of medical problems which would be solved by new developments, even lacking broad markets; and
- d. The potential dollar value of potential markets, taking all three of the previous topics into consideration.

2. In connection with E.1, it may be essential to provide "seed money" somehow to encourage and even enable small manufacturers to turn their attention to innovative efforts, especially to encourage their participation in development of certain specific items related to their established abilities.

3. Where the Government agency itself might expect to use the desired product, either through its direct operating functions, as with the Veterans Administration, or possibly indirectly, as through various Public Health Service granting programs, the agency might be able to suggest a possible or probable market or procurement which would follow production of the desired item. A prosthetic device for limited numbers of VA patients, or a new vaccine for wide public application, would exemplify these two types of approaches.

4. Consideration must be given to more flexible Government policies towards licensing, patents, copyrights, royalties, and other rights for developers of new products when such products are developed under Government contracts or grants. While Government rights must be protected under such circumstances, the attitudes and practices of some agencies are so overly protective or demanding as to discourage some potentially valuable developers from participating under Government R&D programs.

5. Requirements for new products must be stated in terms that are more realistic in terms of both available technologies and potential users' needs. The Workshop noted examples of products which fitted, for instance, certain perceptions of consumer demands, but which, when applied to appropriate clinical settings, failed to gain acceptance by the users, thus negating the time and efforts put into the development by the manufacturers.

6. Just as in B.4, for identifying needs and priorities, the various governmental and private sectors must have ample opportunity to interact in establishing requirements

cited for new health care products. Industry must be consulted as to realistic requirements for production, and the public input must be included to ensure suitability of new products for consumer needs.

7. Greater reliability of new products must be ensured, possibly by institution of new licensing or certification programs, as now accomplished under NBS. Reliability testing must include not only immediate safety and effectiveness measures, but also means to establish longer-range durability and economy of operation; these latter are particularly important in many life-supporting devices or other products.

F. DELIVERY OF HEALTH CARE

The goal of all these several processes is to see the delivery of innovative products to health care delivery systems, for application to the ultimate consumer, i.e., patients. Since this step goes somewhat beyond those of R&D for Innovative Products, the topic for this workshop, we did not address so completely whatever steps might be taken in this final phase of the total process. We did note, however, that rapid advances in the application of new technology to the health care field should not take place without giving adequate attention to the interface between new products and the consumer-patient. In particular it was noted that patient needs must be identified specifically with product needs, and that both must be considered with respect to the in-patient versus out-patient nature of the consumer. Adequate consideration must be given also to interactions of the various delivery components with the patient, through attention to appropriate organization dynamics.

Finally, we consider it of utmost importance to give careful consideration to over-all human values in the application of innovative products to health care delivery systems. While it may be technically and even humanly feasible to introduce various therapeutic regimens, whether by devices, drugs, or other materials, product safety must be considered more important than the speed of application of products to the delivery system. Further, even given the satisfactory nature of this factor, we point finally to the need to keep in high priority the need to maintain above all the dignity of the human being to whom are brought the results of all these technical and production developments. All the potential benefits of technological innovation will come to naught unless we consider of primary importance the need to enhance the quality of human existence of those consumers for whom innovative health care products are created.



workshop 3

**product testing
and evaluation**

PRODUCT TESTING AND EVALUATION

Discussion

The summary which follows does not fully reflect the in-depth discussion which took place in several areas. It attempts to portray the most salient elements of the discussion as a base for conclusions, recommendations, and possibly further study.

Much discussion centered around the extent to which producers of medical devices, in order to protect their reputation as a base for future markets and to satisfy requirements of regulatory agencies, continually test their products. This may include in-plant quality control, prototype testing and evaluating their new developments in the field to ensure that they are marketable and satisfy the needs and demands of their customers. However, this testing and evaluation is not done on a universally organized, uniform and systematic basis, against recognized and accepted predetermined evaluation criteria and performance test standards. Criteria employed is determined on an individual basis by such producers.

Emphasis was placed upon the wide variation in the sophistication and quality levels in medical devices and the problems inherent in efforts by individual hospitals to perform adequate tests and evaluations, to determine the capabilities of products purchased. The circumstances extant in the field of medicines and drugs as related to medical devices was stressed by the representative from the Food and Drug Administration (FDA) as well as current and possible future efforts by FDA to control such devices to assure the safety and efficacy of devices for their intended uses.

It was generally felt that users should play a larger role in establishing performance requirements and evaluation criteria as well as in actual product evaluation prior to procurement. In this regard, it was suggested that evaluation centers and laboratories should be established and/or designated to determine, from the user's viewpoint whether products meet producers claims as well as specific user requirements. Such a service is now being provided for the Department of the Army by the Medical Equipment Test and Evaluation Division of the Army's Medical Material Agency.

It developed quickly from this disclosure that a number of government agencies, including State and local, are testing and evaluating medical devices in varying degrees at various

stages in their life cycle. When added to testing and evaluation by manufacturers and associations, there is a tremendous amount of useful information being developed regarding the relative merits of medical devices, much if not most, of which goes no farther than the boundaries of the organization in which the effort takes place.

Inherent in this widespread and uncoordinated testing and evaluation are duplication, high cost, and varying levels of dependability. Some tests and evaluations are rudimentary and largely subjective while others are more formally designed within objective testing parameters.

Conclusions

1. Medical devices are often selected without benefit of or consideration of specifications that reflect capabilities, design, and performance requirements. Selections are based upon what is recognized in the market, what is currently available, and with some reliance upon the name and reputation of the manufacturer, if known, plus price and salesmanship; price frequently being the predominant factor in any selection.
2. In what often is a highly competitive market, manufacturers may for various reasons take short cuts, not exercise adequate quality control over basic materials, components or the manufacturing process or otherwise cut costs which may lead to product defects in terms of initial or long range performance. It was estimated that 95 percent of the items which should be or are tested are not adequately nor properly tested. In addition to the reasons cited above, there is reliance by some manufacturers upon varying degrees of in-depth research, prototype testing, and production quality control. In any event, it was the consensus of the workshop participants that products should be adequately tested when produced and to some extent throughout their life cycle for reliability and for possible improvements.
3. Agencies conducting formalized testing and evaluation programs for medical devices can serve as a nucleus for cooperative testing. However, this will require coordination, sharing, and widespread dissemination of protocols, test methods, and test results from which credibility can be established progressively. Growth in the use of such test and evaluation results should be consistent with the growth in credibility.
4. The information dissemination process will require centralized coordination if not actual system operation. As a

starting point, a wealth of information based upon a sophisticated approach to testing and evaluation is already available and growing. This could be screened and prepared in the form of digests for dissemination.

5. A listing of government facilities performing any formalized testing and evaluation would facilitate the flow of information among the facilities and between these facilities (agencies) and potential users of test and evaluation results.

6. A listing of tests and evaluations conducted on medical devices and the results in terms of test proven capability should be given high initial priority for dissemination.

7. There is an equally great need for feedback from users of products as an extension of the "in use" test and evaluation process. This should be disseminated to decision making officials and to manufacturers. It has an added advantage of involving users as an integral part of a dynamic and responsive system and as a prime source from which needs can be expressed to procurement officials and to the entire manufacturing community.

8. A ready and reliable source of information from testing and evaluating agencies will support alternative procurement procedures and policies to overcome delays usually facing the introduction of new or more innovative items. It will also be of considerable benefit to manufacturers in initiating design changes to improve products or to overcome deficiencies. It may also provide a basis for totally new devices to satisfy user needs.

9. There should be centralized or cooperative testing of comparability among products which manufacturers claim will perform the same function or functions. Such testing should be based upon a set of characteristics to be measured. Objective and subjective test methods should be developed for the conduct of tests on a uniform and systematic basis. Such information will be invaluable to users in product selection and to manufacturers for product improvement.

10. ETIP can play an important role and one which is consistent with its objectives, by supporting the development of an effective information interchange system as the framework within which more effective and comprehensive cooperative testing and evaluation can evolve. This will in turn create a more favorable environment for developing and marketing innovative products.

Recommendations

1. That an information interchange system be developed with a view initially toward the collection and dissemination of specifications, evaluation criteria, test methods, test and evaluation results, and product comparability test results in the area of medical devices.

2. The range of concerns expressed by participants in this workshop for the most part do not appear to be under the purview of a single Federal agency. There is little to be achieved by recommending actions where there is no known agency to which they can be referred for consideration and implementation. Accordingly, it is recommended that an ad hoc committee be established to design a long range plan for harnessing the efforts of testing and evaluating medical devices. The following areas are among those to which initial effort should be directed.

- a. Compiling a list of agencies currently involved in testing and evaluating medical devices.
- b. Development of purchase specifications.
- c. Development of test protocols and methods.
- d. Development of evaluation protocols and methods.
- e. Development of criteria and system for post-delivery follow-up and user feedback.
- f. The identification of areas for improvement in quality control.
- g. User training and operating and training manuals. (This is important since product performance is related in many instances to operator proficiency.)
- h. The more extensive and cooperative use of Federal, State, and local government laboratories for testing medical devices.
- i. Laboratory accreditation programs such as that of the American National Standards Institute, College of American Pathologists and Communicable Disease Center which may be applicable to the medical devices.
- j. Industry certification programs.
- k. Warranties.

- l. Product safety testing by Underwriters Laboratories and others.
- m. Hospital inspections by various bodies whose functions overlap and require a considerable time span (as related to product selection, installation, and use).
- n. Identification and dating by manufacturers of medical devices as a point of reference for use in long term evaluation.



workshop 4 specifications

SPECIFICATIONS

INTRODUCTION

The primary objective of this workshop was to examine specification practices of Federal, State and local governments in the procurement of medical materiel and recommend methods for obtaining innovative products and systems.

DISCUSSION

Design specifications usually state precise measurements, tolerances, materials, in-process and finished product tests, quality control and inspection requirements, and other information. The procuring activity accepts general responsibility for design and related omissions and deficiencies in the specifications, drawings and bills of materials.

Performance specifications normally state performance characteristics desired for the item and design, measurements, etc. are not stated nor considered to be essential provided performance requirements are met. The contractor accepts responsibility for design, engineering and achievement of stated performance requirements subject to final inspection and approval of product by procuring activity.

Current specifications used in the procurement of the majority of medical materiel by Federal, State and local government agencies are generally design oriented which describe brand name products desired by requesting professional users. Frequently these specifications are modified during the procurement process to afford competition among suppliers and results in describing items which are not available commercially from any manufacturer. Changes in manufacturing practices necessary to meet these unique specifications tend to increase cost of health care delivery system.

The need for increased use of specifications which induce more innovation in design and production of medical materiel is vital. These specifications must provide a means for obtaining products which include the latest technological advancements and meet the professional user's requirements in an economical manner.

Although the dollar value of total Federal Government and State and local government procurement of medical materiel averages less than one-fourth of the annual market, these organizations possess the greatest collective voice in obtaining innovative products.

Special Product Improvement Programs and Research and Development Programs relative to medical materiel are established within some Federal Government agencies. These programs usually apply to special requirements, e.g. military items for use in combat zone, and have limited application in other health care facilities.

Standardization Boards of certain Federal Government and State government agencies develop essential characteristics representing the user's requirements in performance of products. These characteristics are normally transformed into design specifications during the procurement process and fail to encourage innovation in products.

Performance specifications have been used successfully by procurement agencies of the Federal Government, but this practice has not been applied extensively to medical items. Industry does respond favorably to performance demands of users in producing medical items or other commodities which are marketable.

Implementation of optimum system(s) for providing medical materiel support to all Federal Government activities is currently moving toward actual reality. The achievement of effective and economical support which is responsive to users of medical items is the ultimate objective of this project. It includes increased commonality of medical items and centralized procurement management prescribing practices which provide incentives to the health care industry for delivery of the most suitable product at the lowest cost.

The application of value management techniques in detailing specifications and evaluating manufacturer's proposals is slowly increasing in the Federal, State and local governments. These procedures greatly enhance the capability of procuring products at the lowest cost consistent with requirements for performance, reliability, quality and maintainability.

A need exists for a central repository of medical materiel specifications, standards, test protocols and test results for use by all Federal, State and local government activities, as well as the private sector. The National Bureau of Standards has a library of over 200,000 Federal, State, local and technical associations' specifications and standards.

Veterans Administration/ETIP recently developed a listing of 61 major items susceptible to procurement incentives for encouraging innovations in health care products. Through an evaluation process, 12 items were placed in highest priority to be obtained through procurement methods utilized to stimulate innovations at the marketplace. Methodology for

development of innovative products and systems was developed by VA-ETIP and action has been initiated on two items. Coordination of these procedures or selection of items concerned was not accomplished with other Federal, State, or local government medical logistical agencies.

RECOMMENDATIONS

1. Performance specifications provide the most effective means of stimulating innovative design and construction of products by the health care materiel industry. These specifications should include:

a. Performance criteria based on input from professional users of materiel.

b. Only those design characteristics which are absolutely necessary to insure procurement of item desired.

c. Life cycle costing and value incentive clauses to insure quality products having meaningful service life are procured at the lowest cost.

d. Testing and evaluation methods to be utilized in determining conclusively that products meet all clinical, laboratory, safety, maintenance, life expectancy and other requirements.

2. ETIP should serve as the catalyst in developing performance specifications for appropriate medical items or systems. This type specification should be prepared in conjunction with appropriate Federal, State, and local governments and industrial organizations. Consensus mechanism should be used to develop and communicate these specifications.

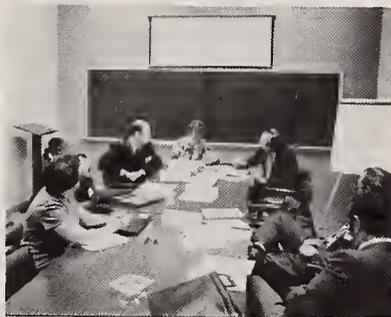
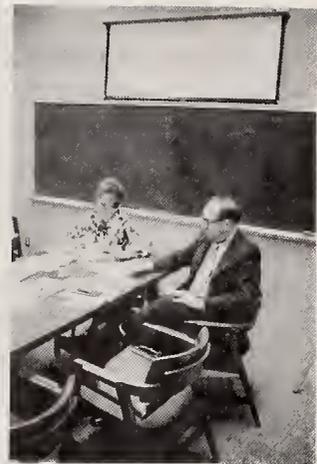
3. ETIP should evaluate the expansion of NBS Standards Information Office to serve as central repository for standards, specifications, test protocols and test results concerning all medical materiel. This recommendation will provide a recognized organization having a library of technical material available to Federal, State, local and industrial activities concerned with logistical support of health care delivery systems and result in reduced costs of medical care.

4. ETIP should survey other appropriate Federal, State and local government activities to provide additional performance and requirements data relative to Bedpan Sterilizers and Hypodermic Devices Destructors. It is recognized that procurement of these two items is in final phase but it is

considered that this additional information will solidify these actions.

5. VA-ETIP should coordinate with appropriate Federal, State and local government agencies future actions on all other items within their program to solicit additional information concerning evaluation of current applicable products and suggested performance and testing criteria. This recommendation will eliminate duplication of effort and provide greater support for ETIP.

6. ETIP should monitor a Task Force for development of performance specifications concerning Surgical Gloves and Examination Gloves. The Task Force is composed of Mr. George Ainsworth (Hospital Bureau Inc. of N.Y.), Chairman; Mr. Wilbur Balderson (Department of Defense); Mr. Alan Wonhof (Veterans Administration); Mr. James Arnold (City of Chicago/Cook County Hospital); Mr. Donald Carte (State of West Virginia); and Mr. Ross Hofmann and Mr. Anthony Zolenas (Ross Hofmann Associates). Methodology established by VA-ETIP for development of innovative products will be followed by the Task Force. Detailed information concerning user complaints, procurement practices, methods of testing and average demands for each size glove will be provided to the Chairman by each Task Force member. The Chairman will develop a draft of performance specifications for review by all members and prepare final proposed specifications based on comments resulting from coordinated actions. This data will be provided to VA for use in a test procurement of gloves. Applicable documents will be identified as ETIP Experimental Procurement and a pre-bidders conference will be held with qualified representatives of industry to outline ETIP concepts and potential procurements which may result from valid performance specifications. Each member will participate in evaluating all aspects of the development and evaluation of this initial interagency test of applying ETIP principles to medical materiel.



workshop 5
post delivery
performance,
warranties and
training by
vendors

POST DELIVERY PERFORMANCE, WARRANTIES AND TRAINING BY VENDORS

This report will include an exposition of the charge to and the methodology employed by the Workshop groups. Also covered will be highlights of discussions and recommendations.

Responsibility

The Workshop was responsible for the analysis of current practices in the area of post delivery performance. Specifically included were the topics of warranties, instruction manuals, instruction programs, cost of instruction and parts lists. Analysis was preparatory to the development of recommendations for improvements in current practice. Recommendations were to include suggested ETIP sub programs for the implementation of improvements.

Composition

There were two Workshop groups. One represented a first choice group while the other represented second choices. The groups were balanced in composition. Representation from the public and private hospital sector and the vendor community was evident. This balance was essential to the success of the Workshop. Varied viewpoints and backgrounds provided complete insight into problems. The resultant recommendations represented a consensus accounting for the rights and obligations of both user and provider. It is recommended that ETIP consider:

This balance in future symposia;

The inclusion of this balance in an ongoing fashion via the addition of an ETIP advisory staff.

Methodology

The groups were structured sufficiently to provide for a maximum of interplay while accomplishing objectives. Structure consisted of the following sequence employed with each group:

Co-chairpersons introduced the group to the purpose and overall discussional parameters of the Workshop;

Participants introduced themselves;

A co-chairperson introduced a specific topic, specified an optimum length of discussion time and informed the group that at the end of discussion a preliminary summarization with recommendations would be required;

The group discussed the topic;

A summary was provided;
Recommendations were proposed, discussed and adopted;
The group proceeded to another topic.

It is recommended that ETIP consider the inclusion of this or a similar methodology as a standard recommended structure for future symposia.

Topics

The statements and recommendations listed below represent the consensus of the Workshop groups after discussion and debate.

Warranties

There is no inflexible rule for the time frame of warranties. The length should be variable. Its extent is dependent upon the purpose and nature of the equipment. As a minimum it should cover a period sufficient to establish the equipment's ability to perform.

Post delivery warranty problems can be avoided by recognizing the importance of warranties. If significant pre-purchase emphasis is placed by buyer and seller on this topic, greater understanding of extent can be achieved prior to delivery. Contract changes can be effected prior to purchase to preclude post delivery conflict.

An extension of warranties is the safety certification of equipment by independent agencies and/or regulatory bodies. The process of certification can be lengthy and when so radically extends the time frame with which new technology proceeds from development to the delivery stage. Expedition of certification, while maintaining standards, is desirable.

It is recommended that ETIP consider the creation of an experimental program to develop means by which certification can be expedited.

Manuals

Operation and parts manuals are essential. Consideration must be given to the language and level of composition prior to purchase and requirements clearly stipulated in the purchasing instrument.

Operating instructions should be in illustrated form and be clearly posted on the surface of equipment. A stock of repair parts should be maintained by manufacturers for the service life of the equipment as a minimum.

Training

The manufacturer or vendor should be responsible for demonstration on the proper use of equipment. The purchaser should be responsible for specifying prior to purchase the type, location and extent of training.

There is an absence of uniform and universal standards for the certification of medical equipment operators. In view of the sophisticated, complicated and life saving nature of this equipment, some form of uniform standard should be universally applied.

It is recommended that ETIP consider the establishment of a research project to investigate the development of national standards for training, testing and certifying medical equipment operators.



workshop 6
cost saving and
quality improve-
ment through
innovative
products

COST SAVINGS AND QUALITY IMPROVEMENT
THROUGH INNOVATION PRODUCTS

The opening session was a general discussssion of the following:

1. Cost savings vs. quality care - quality care must be maintained at a high level, safety of product is the number one priority, and cost is carefully evaluated if the other specifications are met.
2. Disposables vs. Reusables - since the market is abundantly supplied with all types of disposable products and equipment, careful assessment of each item must be made as to safety, packaging, cost, usage, inventory and disposal as opposed to cost, safety, usage, inventory of reusables, keeping in mind increasing cost of the labor market for reprocessing.
3. Standardization - those present felt that there is an urgent need to standardize materiel and equipment for all types of health care facilities as a means of cost containment. Several areas were discussed as to how this could be best accomplished. Some felt that a government agency could set standards for all to follow, while others opposed the idea. Some were of the opinion that competition was necessary for fair pricing on the open market and to maintain quality control. Standardization should begin at home to be effective and then move out into the health care field.
4. Baseline for costs - most present felt there was no baseline from which to work and there was a basic need for this. It could be accomplished through communication, through other groups to define common problems, some basic methods for specifications, and that the needs of the health care field be projected to industry for less duplication to conserve costs and improve quality.

These discussions were on interchange of ideas and concepts on a frank and friendly basis. It laid the base or foundation for the discussions at the next sessions so that the problems could be defined and solutions be found.

Wednesday's sessions were spirited and informative - not always a matter of seeing eye to eye with one's neighbor.

Through constructive interchange and discussion the following recommendations were proposed by the workshop:

1. Specifications.

Performance standards where possible, rather than specific standards or design standards for better price and quality.

The workshop group provided a consensus in favor of performance standards wherever possible. Many people involved in health care agree that a performance standard, particularly in areas involving expensive equipment and systems, can provide the health care facility with cost containment means of implementing requirements. It is also important to note that while the value of innovation is generally recognized, the possibility and probability of benefiting from innovations by the manufacturer, and in some cases, the hospital itself is greatly enhanced by performance standards.

2. Dating of Medical Supplies.

All sterile supplies need to have an expiration date affixed to the package.

Dating of any item should not increase the acquisition cost.

In order to maintain a current, safe and in date inventory, the need for an affixed expiration date on the package is imperative. This assists in inventory control by proper rotation of stock, never having old items on the shelf, and thus eliminates obsolescence. An increase in the price of the item on the market place should not be tolerated by the user simply because it is dated. Dating of supplies is a safeguard for industry and health care users in providing quality care as well as means of cost containment.

3. Health Care Equipment - such as carts, stands, shelving, etc.

Equipment of this nature should be constructed of materials selected on a basis of performance.

Performance requirements should consider structural strength, electrical safety, and microbiological integrity. While stainless steel historically appears to be a material of choice, performance standards should permit and encourage the use of other equal or more suitable materials which can

provide equal practical durability with enhanced electrical safety, resistance to organism growth, cleanability, and noise attenuation. Examples can be found in some of the coated steel products and in some cases application of plastic laminates.

4. Industry and Health Care Users.

A clearinghouse should be established for the receipt of any ideas and for their dissemination to health care facilities, manufacturers of health care products, health care providers and users, inclusive of government, industry and health care associations. A forum of this nature should enable dialogue of all sorts and include the magnetism for practical discussion of suggestions, ideas, and complaints.

The workshops recommended an approach to a continuing dialogue between industry, government and providers and it is recommended that the machinery for such a forum be set up and administered by the Experimental Technology Incentives Program of the National Bureau of Standards.

It is also recommended that a sample workshop would be feasible to promote dialogue between industry, health care providers, and users at the next symposium with selected subject matter posted well in advance.

The workshop felt that future sessions could be enhanced by making an effort to include representation of the State Hospital Association in the program.

Where possible, it is recommended that future symposia be scheduled in coordination with the National Code and Standard Making Agencies.

A significant indication of this symposium was the unanimous recommendation for the establishment of such a clearinghouse and opportunities to pursue such a venture.

Another objective in cost containment was discussed at length - Value Incentive Clause in contracts with manufacturers, but due to its complex nature, the workshop voted not to recommend it. There was a fear that quality of products could be lost.

CLOSING REMARKS

Joseph G. Berke
Experimental Technology Incentives Program
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As I sat here trying to take a series of notes on the outputs of all the workshops, I got so engrossed in listening that I didn't take as many notes as I probably should have.

It became pretty obvious throughout the discussion that there were two major aspects that will require attention that I hope ETIP, through our experiments, can take care of. One is the whole communications problem and the other is the development of performance specifications. I would like to tie into some of the recommendations that were given and how we are working towards addressing some of these and where we are going from here. As far as the communications goes, first of all, everybody here will receive the report of this symposium, the reports of all the co-chairpersons, of all the workshops fully included with a list of the workshop participants. Secondly, any information about any of our experiments that are going on with the Federal Supply Service and with state and local governments, is available to anybody who wants it. The information is available by writing to us, or to the Federal Supply Service directly. We have identified a heading at the National Technical Information Service (NTIS) related to all ETIP experiments. As soon as possible, we will begin putting all of these reports and project findings into NTIS so you can get them.

On a broader scale, you who heard Dr. Ambler talk about the other work the Bureau is doing in surgical implants, compatibility of plastics and body fluids, standard reference materials, etc. If you wish to know anymore about NBS's medically related work, please write and we will do our best to get you that information.

As far as keeping you informed on the various projects, we are trying to develop a product information sheet that will be updated every time there is a change in the procurement process, anytime there are new findings, and anytime there is something to report. These project sheets will also be available upon request.

It is interesting to note that the "communications media" discussed, although not specifically, is basically a procurement document, I think that is where the procurement part of ETIP is going to find the greatest challenge of all. That is, to communicate through the procurement documents,

the real needs and desires of the users and get industry to respond. We are trying to use these initial experiments, medical, non-medical, Federal, state and local, to find out just exactly what is needed in a product information package, if you will, that can eventually go into a major communications system that you have all been talking about. The need, of course, is there, the specifications that you want should be in there, based on everybody's input. The possible size of the market, Federal, state and local, so that industries can tap the data base and if its a generic product, you will be fairly confident that the VA hospital and the Kaiser Hospital in San Francisco and Doctors Hospital in San Jose for that generic item will at least use 75% of that specification; the other 25% being regional differences or personal desires, but at least most of the specification is there. And you will know what the market is, test methods, and possibly a section on procurement policy; how the item was bought. You can have a performance specification and you can buy it many different ways, with a Life Cycle Costing feature or a multiple award feature or the Value Incentive Clause feature. This should provide some rationality and continuity in the procurement process used at all levels, where possible, for generic products. This kind of a product list, the content of a product experiment, could form the basis for the input to this major communications data base. We are already doing something like that in the non-medical products going on at Federal, state and local through our experiments and we hope to do the same thing, a similar format, in all our medical experiments to make it as easy as possible. If any of you ever see a product sheet, if any of you ever have any comments on it, what it should contain, maybe it should contain more for one type of industry than another, please let us know.

Once again, about the future symposium. We would like, of course, to have all of you who are here fill out the questionnaire, pick some dates, hopefully not conflictng with the myriad of other health related conferences and things going on around the country, which apparently this one conflicted with. We're also under the gun of having to reserve very early in the Bureau, because we run something like 50 conferences a year and if we don't pick June, the next opening is sometime the latter part of the year. Spread the word if this is informative to you, put down things you would like to see changed and we would love to have the suggestions and run another symposium.

ETIP also has, for those of you interested, a traveling booth that we can put up or loan to interested groups who would like to have the ETIP concept displayed at your

particular show or convention. We can make the booth available to you to staff with your people or somebody from ETIP could co-person it with you and spread the word that way. Let us know. If any other information is necessary or if we can help in any way in providing you with documents or be of assistance in publicizing this through your own professional association magazines, journals, and articles, please let us know. Keep in mind that ETIP is the catalyst in trying to get the experiment on its way, the VA deserves a great deal of credit and will be doing most of the real world interaction with the users and with the industry and I'm sure they would also appreciate any input you might have in making their job easier. When an invitation for bid with a performance specification comes out, don't jump all over them. Think of it as an experiment and help VA make it better.

I hope you have found this a worthwhile symposium. I know I've enjoyed it. Based on some of the conversations I had last night a lot of people thought it started off slow, but then really took off. I was very encouraged by what I heard. We will try to run the experiments that all of you suggested.

So, to wrap it all up, ETIP and the VA and all other participants in our state and local programs stand ready to carry out these experiments, provide the information and hopefully recommend policy changes that will benefit all of you in bringing together a more rational purchasing procedure and causing a higher rate of technological change. Thank you.

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| 16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.) The general objectives of the conference were to investigate ways for improving interaction between health care personnel and the manufacturers of hospital products and systems, so that the demands of all hospitals for improved and innovative products and systems can be more adequately met; to explore various means available for encouraging innovation and more efficient technological change: from initial research, through product development, user testing and evaluation, marketing and purchasing, to post-delivery assistance for the using services; to develop approaches that will permit hospitals to acquire the latest technologies more expeditiously and economically through the procurement process. Workshops were organized to consider procurement mechanisms, information interchange, testing and evaluation of medical products, and the interrelationship between marketing, R&D and procurement. Workshops were grouped as follows: (1) Interaction Between the Hospital User and the Industry Supplier, (2) Research and Development for Innovative Products, (3) Product Testing and Evaluation, (4) Specifications, (5) Post Delivery Performance, Warranties and Training by Vendors, (6) Cost Saving and Quality Improvement Through Innovative Products. | | | | |
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